

## AMENDMENTS

### Listing of Claims

The following listing of claims replaces all previous listings or versions thereof:

1. (Currently amended) A method for evaluating the risk of irinotecan toxicity in a patient comprising determining ~~the presence of a polymorphism whether the nucleotide at position -3279 is a G or T~~ in one or both *UGT1A1* genes of the patient, ~~wherein the polymorphism is in linkage disequilibrium with a *UGT1A1* TA repeat~~ and evaluating the risk of irinotecan toxicity in said patient based on the presence or absence of T or a G at position -3279.
2. (Currently amended) The method of claim 1, further comprising amplifying ~~from a nucleic acid sample all or part of 5' flanking a~~ region of one or both *UGT1A1* genes to obtain amplification products and ~~analyzing the amplification products for the presence or absence of a polymorphism~~.
3. (Canceled)
4. (Currently amended) The method of claim 1, ~~wherein further comprising determining the number of TA repeats is 5, 6, 7, or 8 TA repeats~~ in the promoter of one or both *UGT1A1* genes.
- 5-9. (Canceled)
10. (Currently amended) The method of claim ~~[[5]]~~1, further comprising determining the ~~presence of a polymorphism whether the nucleotide at position -3156 is a G or an A~~ in one or both *UGT1A1* genes of the patient, ~~wherein the polymorphism is a -3156G>A polymorphism~~.
11. (Canceled)

12. (Currently amended) The method of claim ~~[[11]]~~10, further comprising classifying the UGT1A1 activity level in the patient, ~~whereby identification of a guanine residue indicates the patient does not have a low level of activity.~~
13. (Currently amended) The method of claim ~~[[11]]~~10, further comprising determining the nucleotide sequence at position -3156 of a ~~second~~both ~~UGT1A1 gene~~genes in the patient.
14. (Currently Amended) The method of claim 11, further comprising administering irinotecan to the patient if a guanine nucleotide is found at position -3156.
15. (Original) The method of claim 1, further comprising analyzing a glucuronidation rate ~~associated with the polymorphism.~~
16. (Currently amended) The method of claim 1, further comprising ~~optimizing~~adjusting a dose of irinotecan ~~for administration~~administered to the patient.
17. (Currently amended) The method according to claim 1, wherein determining the ~~presence of a polymorphism of anucleotide at position -3279 of the~~ UGT1A1 gene or genes is performed by a hybridization assay.
18. (Currently amended) The method according to claim 1, wherein determining the ~~presence of a polymorphism of anucleotide at position -3279 of the~~ UGT1A1 gene or genes is performed by a sequencing or microsequencing assay.
19. (Currently amended) The method according to claim 1, wherein determining the ~~presence of a polymorphism of anucleotide at position -3279 of the~~ UGT1A1 gene or genes is performed by an allele-specific amplification assay.
20. (Original) The method of claim 1, further comprising administering to the patient irinotecan.

21. (Currently amended) The method of claim 20, further comprising administering to the patient a ~~second~~ agent to ~~reduce~~that reduces excretion of an active irinotecan species through the bile.
22. (Currently amended) A method for evaluating the risk of irinotecan toxicity in a patient comprising ~~[[:]]determining whether the nucleotide sequence at position -3279G>T is a G or a T and whether the nucleotide at position -3156 is a G or an A in at least one UGT1A1 gene of the patient, and evaluating the risk of irinotecan toxicity in said patient based upon the presence or absence of a G or a T at position -3279 and the presence or absence of an A or a G at position -3156.~~
23. (Currently amended) The method of claim 22, further comprising classifying the *UGT1A1* activity level in the patient, ~~whereby identification of a guanine residue indicates the patient does not have a low level of activity.~~
24. (Previously presented) The method of claim 22, further comprising determining the nucleotide sequence at position -3156 of a second *UGT1A1* gene in the patient.
25. (Previously presented) The method of claim 22, further comprising administering irinotecan to the patient if a guanine nucleotide is found at position ~~-3516~~-3156.
- 26.-33. (Canceled)
34. (New) The method of claim 4, wherein the number of TA repeats is 5, 6, 7, or 8.
35. (New) The method of claim 22, further comprising determining the number of TA repeats in the promoter of one or both *UGT1A1* genes.
36. (New) The method of claim 35, wherein the number of TA repeats is 5, 6, 7, or 8.